K073271

510(k) Summary Agfa OrthoGon

Agfa OrthoGon

Common/Classification Name: Picture Archiving and Communications System (PACS), 21 CFR 892.2050
Proprietary Name: OrthoGon

DEC 05 2007

Agfa HealthCare Corporation
10 South Academy Street
Greenville, SC 29602-9048

Contact: Tom Holbrook, Prepared: November 2, 2007
Telephone: (519) 746-6210 ext. 3297
Facsimile: (519) 746-3745

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's OrthoGon software. The predicate devices are Agfa's previous orthopedic application; Orthopedic Software for Impax® Workstations (K071972) and OrthoCrat Limited's TraumaCAD (K042816). The new device is similar in indications and has the same intended use as the predicate devices.

B. DEVICE DESCRIPTION

OrthoGon, the new device, is similar in principals of operation and technology to the predicates. All are software devices that run on commercially available computer systems.

OrthoGon assists physicians in their analysis of anatomy and pathology by providing easy to use, interactive measurement schemes.

OrthoGon allows the user to easily perform standard measurements and to compare results to prior measurements and to normal values from the medical literature.

OrthoGon uses X-ray images based on the DICOM standards. The device is compatible with multiple PACS workstations and software versions.

OrthoGon allows the user export results into Excel formatted reports.

C. INTENDED USE

OrthoGon is a plug-in application for PACS workstations. The package is intended to assist clinicians in their analysis of anatomy and pathology by providing interactive 2D measurement schemes and comparisons against

prior measurements and against normative references to aid in the diagnosis of disorders and deformities.

OrthoGon is intended for use primarily in the field of musculoskeletal radiology, orthopedics, trauma and pediatrics using 2D X-ray images based on DICOM standards.

The application is intended for use by radiologists, radiographers, technologists, referring physicians and orthopedic surgeons and can be used in operating theaters, mobile and military environments.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's OrthoGon Software has similar indications and the same intended use as the legally marketed predicate devices.

The differences do not modify the intended diagnostic or therapeutic effect. It is intended to assist clinicians in their analysis of anatomy and pathology by providing interactive 2D measurement schemes and comparisons against prior measurements and against normative references to aid diagnosis of disorders and deformities.

OrthoGon is used primarily in the fields of musculoskeletal radiology, orthopedics, trauma and pediatrics.

Descriptive characteristics and data provided in this submission are sufficiently precise to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same in the proposed and predicate devices. All devices use similar, commercially available, computers with Windows® operating systems. All operate on DICOM images. All use interactive measurement "wizards" to guide the user in selecting anatomical landmarks. All allow comparison to normative data from the medical literature

F. TESTING

OrthoGon has been tested for compatibility with Agfa's Impax® PACS Systems.

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 05 2007

Agfa HealthCare Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K073271
Trade/Device Name: Agfa OrthoGon
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 9, 2007
Received: November 21, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Agfa OrthoGon**
Indications for Use:

OrthoGon is a plug-in software application for PACS workstations. The package is indicated to assist clinicians in their analysis of anatomy and pathology by providing interactive 2D measurement schemes and comparisons against prior measurements and against normative references to aid in the diagnosis of disorders and deformities.

OrthoGon is intended for use in the fields of musculoskeletal radiology, orthopedics, traumatology and pediatrics using 2D X-ray images based on DICOM standards.

The application is intended for use by radiologists, radiographers, technologists, referring physicians and orthopedic surgeons and can be used in operating theaters, mobile and military environments.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073271